HIGH TORQUE BALLOON CATHETER POSSESSING MULTI-DIRECTIONAL DEFLECTABILITY AND METHODS THEREOF

CROSS-REFERENCE TO RELATED APPLICATIONS

[001] This application is a continuation-in-part of U.S. patent application Ser. Nr. 09/878,689 filed on June 11, 2001, now U.S. Pat. No. 6,611,720, which is a continuation-in-part of U.S. patent application Ser. Nr. 09/372,484 filed on August 12, 1999, now U.S. Pat. No. 6,246,914.

FIELD OF THE INVENTION

[002] The present invention generally relates to improved constructions for a deflectable, high torque, balloon catheter. More particularly, this invention relates to methods and catheters for diagnosing and treating cardiac arrhythmias via a multi-directional, deflectable, torque transmittable cardiovascular balloon catheter by mapping and stimulating the human heart with contrast medium injection, pacing, cardioversion, defibrillation, and/or radiofrequency ablation therapy.

BACKGROUND OF THE INVENTION

[003] Symptoms of abnormal heart rhythms are generally referred to as cardiac arrhythmias, with an abnormally rapid heart beat being referred to as tachycardia. The present invention is concerned with the treatment of tachycardias that are frequently caused by the presence of an "arrhythmogenic site" or "accessory atrioventricular pathway" close to the surface of the upper chambers of a heart. The heart includes a number of normal pathways that are responsible for the propagation of electrical signals from the upper chamber to the lower chamber necessary for performing normal systole and diastole functions. The presence of arrhythmogenic

site or accessory pathway can bypass or short circuit the normal pathway, potentially resulting in very rapid heart contractions, referred to here as tachycardias.

[004] Treatment of tachycardias may be accomplished by a variety of approaches, including drugs, surgery, implantable pacemakers/defibrillators, and catheter ablation. Catheter based radiofrequency ablation is generally performed after conducting an initial electrophysiology study where the locations of the arrhythmogenic site and/or accessory pathway are determined. Electrophysiology study and temporary defibrillator/cardioverter involve catheters having at least one electrode means for the delivery of low energy pacing pulses directly to the heart tissue at various intervals or frequencies in order to induce the arrhythmia. Once the arrhythmia is induced, it must be terminated by typically delivering a high-energy defibrillation shock across the patient's chest with paddles. A specific very high therapeutic voltage is required within the heart to terminate the induced arrhythmias. The voltage delivered through a conventional transthoracic defibrillator paddle from outside the body is substantially greater than the necessary therapeutic voltage because it needs to compensate for the energy losses through the skin and the thoracic cavity. An internal or tranvenous defibrillator/cardioverter from a catheter poses less risk and higher therapeutic efficiency.

[005] A transvenous catheter that combines the functions of the rate sensing, pacing, and defibrillation has a plurality of electrodes on a distal portion. The catheter should have multi-directional deflectability and high torque so that it can be guided to the exact location of the heart tissue for pacing, cardioversion, defibrillation and/or radiofrequency ablation. The catheter should also be flexible enough for insertion into a body and have adequate surface for contacting the intracardiac tissues. Some examples of cardioverter and methods are U.S. Pat. No. 5,005,587 to Scott, No. 5,766,224 to Alferness et al., No. 5,814,081 to Ayers et al., No. 5,810,887 to Accorti, Jr. et al., and No. 5,913,887 to Michel. Because of the exact location requirements, the deflectability and torque transmission properties of a catheter to ensure that a substantial fraction of the rotational and displacement forces provided along the catheter are translated to rotational and displacement forces at the distal end of said catheter become very

important. Furthermore the catheter is placed inside orifices or ostia such as the coronary sinus or pulmonary vein ostium, and the vessel opening is temporarily blocked with an inflatable balloon just proximal to the distal tip prior to injection of contrast media through its internal lumen for determining vessel size and configuration.

[006] Another particular interest point to the present invention is radiofrequency (RF) ablation protocols that have proven to be highly effective in tachycardia treatment while exposing a patient to minimal side effects and risks. After a mapping study, an ablation catheter is usually introduced to the target heart chamber and is manipulated so that the ablation tip electrode lies exactly at the target tissue site. Radiofrequency energy or other suitable energy is then applied through the electrode to the cardiac tissue in order to ablate the tissue of arrhythmogenic site or the accessory pathway. By successfully destroying that tissue, the abnormal conducted signal patterns responsible for the tachycardia can be eliminated. In the case of atrial fibrillation (AFib), multiple arrhythmogenic sites and/or multiple accessory pathways exist. It becomes desirable that a long linear lesion or a broad lesion zone at the tissue contact sites to ensure appropriate energy delivery.

[007] Scott in U.S. Pat. No. 5,005,587 discloses a braided electrode lead in an endocardial pacing and defibrillation catheter having an elongated hollow polyurethane shaft. Although providing good stiffness and biocompatibility, the polyurethane tube lacks sufficient translation between the rotational and displacement forces applied along the body of the polyurethane tube. Accorti Jr. et al. in U.S. Pat. No. 5,810,887 discloses a catheter having a braided wire section for torque transmission. For the purposes of cardioversion and defibrillation, the surface contact area becomes very critical. With regards to the braided wire section, only the outer radial surface of the braided section is employed in contacting a tissue. In other words, the effective tissue-contacting surface of wires in the braided wire section is sub-optimal as compared to an essentially flat surface. The braiding of wires also makes the braided wire section undesirably rigid.

[008] Similarly, Michel in U.S. Pat. No. 5,913,887 discloses a transvenous device having three coil electrodes for cardioversion of atrial flutter or atrial fibrillation. The tissue-contacting surface area of a coil electrode is less than an essentially flat surface. The coil electrode also suffers a drawback of less torque transmission property. None of the conventional temporary catheters for cardioversion/defibrillation has a steerability property.

[009] While tranvenous cardioversion procedures using an existing catheter design have produced some promising results, the bending and torque transmission properties, the effective tissue-contacting surfaces, and rigidity of a conventional catheter usually do not meet the clinical requirements. Additionally this multi-bending property facilitates insertion of the catheter distal section into specific cardiac vessels and improve the balloon placement. Therefore, there is an urgent clinical need to have a flexible, balloon catheter that also possesses multi-directional deflectablility and high torque transmitting property to be used in internal cardioversion procedures.

SUMMARY OF THE INVENTION

[010] The present invention provides an improved deflectable and high torque balloon catheter that can be used in the procedures of mapping by contrast medium injection and stimulating the human heart with pacing, cardioversion, defibrillation, and/or radiofrequency ablation therapy. It is one object of the present invention to provide a flexible catheter with high torque transmission properties. It is another object of the present invention to provide a flexible catheter with a slit tubular element that has a plurality of rows of slits and anchors on said slit tubular element. It is still another object of the present invention to provide a flexible catheter with a slit tubular element that has at least one continuously spiraling slit with longitudinal rows of anchors on said slit tubular element. The word "slit" is defined as a straight or curved narrow cut or opening on a substrate in this patent application. It is yet still another object of the present invention to provide an inflatable balloon on the distal end of the catheter to temporarily block vessel orifice and to provide a separate lumen to enable contrast media injection though the open distal tip for improved anatomical visualization under fluoroscopy.

[011] In one embodiment, a deflectable, high torque catheter comprises a flexible catheter shaft having a distal shaft section, a proximal shaft section and at least one middle shaft section, wherein each shaft section has a distal end and a proximal end, and wherein the shaft section is secured to its adjacent shaft section, said flexible catheter shaft having at least one lumen extending between the distal end of the distal shaft section and the proximal end of the proximal shaft section. A handle may be secured at the proximal end of the proximal shaft section. The catheter further comprises at least one shaft section comprising a deflectable, high torque transmission assembly for transmitting deflectability and torque along said at least one shaft section, said deflectable and high torque transmission assembly comprising a slit tubular element that has a plurality of staggered rows of slits and anchors on said slit tubular element and has sufficient deflectability and torque properties ensuring that a substantial fraction of the rotational, displacement, and bending forces provided along said at least one shaft section are translated to rotational, displacement, and bending forces at the distal end of said shaft section of

the flexible catheter shaft. The deflectable, high torque catheter of the present invention is equally useful as either a non-energy delivery catheter or an energy delivery catheter.

[012] In another embodiment, said deflectable and high torque transmission assembly comprises a slit tubular element that has at least one continuously spiraling slit on said slit tubular element and has sufficient bending and torque properties ensuring that a substantial fraction of the rotational, displacement, and bending forces provided along said at least one shaft section are translated to rotational, displacement, and bending forces at the distal end of said shaft section of the flexible catheter shaft, wherein the slit tubular element has a plurality of parallel, staggered rows of slit members and anchors resulting from the at least one continuously spiraling slit.

[013] In a preferred embodiment, the arrangement of said plurality of staggered rows of slits with respect to a longitudinal axis of said shaft section of the catheter may be selected from the group consisting of a perpendicular slit, an angled slit, a curved slit, and a combination of the above thereof. Furthermore, each of the plurality of slits has a slit starting point at an outer surface of said shaft section and two slit terminating points at said outer surface away from the slit starting point, wherein the distances from said slit starting point to each of the two slit terminating points are about equal. In a further embodiment, the at least one slit terminating point is coupled with a small circular hole for even stress relief, especially when the slit tubular element is bent in one direction or the opposite direction.

[014] In a particularly preferred embodiment, the slit tubular element of the deflectable, high torque transmission assembly is embedded within an elastic membrane, is covered on an inner side of the slit tubular element, or is covered on an outer side of the slit tubular element by an elastic membrane. In one embodiment, the elastic membrane is to separate the interior lumen of the slit tubular element from an exterior surrounding of said slit tubular element. The elastic membrane may be selected from the group of elastic material or expandable membrane consisting of silicone, latex, polyurethane, thermoplastic elastomer such as Pebax

brand polyether block amides, polyethylene balloon, cross-linked polyethylene balloon, permeable membrane, polyethylene terephthalate balloon, and the like. The slit tubular element may be made of a material selected from the group consisting of polypropylene, polysulfone, platinum, stainless steel, Nitinol, gold, silver, iridium, tungsten, and their mixture thereof.

[015] The deflectable, high torque catheter of the present invention further comprises a RF energy generator and an electrical conductor secured to said RF energy generator and said slit tubular element, wherein the electrical conductor is adapted for transmitting RF energy from said RF energy generator to the slit tubular element which is constructed of a conductive material. The high torque catheter further comprises at least one electrode mounted on the catheter shaft that is adjacent to the slit tubular element. The at least one electrode and/or the slit tubular element may be used for sensing, pacing, cardioversion, defibrillation and RF energy delivery.

[016] In still another embodiment, the catheter further comprises a steering mechanism on the handle for deflecting the distal section of the catheter. One end of the steering wire is usually secured at said steering mechanism, while the other end is secured at a distal point on the inner side of the distal shaft section; in between the two ends, the steering wire travels through a row of anchors inside the said slit tubular element for deflecting the distal portion of said flexible high torque catheter in one specific plane. The catheter may further comprise other steering wires traveling through other rows of anchors attached to the slit tubular element to allow deflectability in other planes. The catheter may further comprise a plurality of deflectable curves on the distal tip section of the catheter shaft being provided by the steering mechanism on the handle. The catheter may still further comprise an internal lumen extending from the handle end to the distal tip for fluid injection (i.e., contrast media) and another separate lumen for inflating a balloon at the catheter distal end for engaging an ostium (i.e., coronary sinus and pulmonary vein). By providing a steerable catheter with a plurality of multi-directional, deflectable curves, the electrodes of the catheter on the distal section can fit into the vessel more easily and facilitate and enhance the vessel visualization by contrast medium injection while the

inflated balloon is placed over the vessel orifice. The steering mechanism is well known to those who are skilled in the art. However, incorporation of a multi-planar, steering mechanism into a high torque, balloon catheter of the present invention is unobvious.

[017] A method for operating a deflectable, high torque balloon catheter within a body of a patient may comprise the steps of: (a) percutaneously introducing the deflectable, high torque catheter through an opening of the body of the patient; (b) approaching the deflectable, high torque catheter to a target tissue of the patient by transmitting rotational and displacement forces through the at least one shaft section of the flexible catheter shaft; and (c) positioning the deflectable, high torque balloon catheter at the target tissue for diagnostic study by use of balloon for blocking vessel ostium, followed by contrast medium injection through its distal tip, and/or therapeutic tissue treatment with radiofrequency or low energy defibrillating energy. Said deflectable, high torque, balloon catheter comprises a flexible catheter shaft having a plurality of shaft sections, wherein at least one shaft section comprises a high torque transmission assembly for transmitting torque along said at least one shaft section, said high torque transmission assembly comprising a slit tubular element that has a plurality of rows of slits and anchors on said slit tubular element and has sufficient torque properties and multi-directional deflectability ensuring that a substantial fraction of the rotational, displacement, and bending forces provided along said at least one shaft section are translated to rotational, displacement, and bending forces at a distal end of said shaft section.

[018] The method and apparatus of the present invention have several significant advantages over known conventional catheters or techniques, particularly the flexible and multi-directional deflecting slit tubular element on at least one shaft section of the flexible catheter make the balloon catheter particularly useful in procedures for mapping purposes and for stimulating the human heart with pacing, cardioversion, defibrillation, and/or radiofrequency ablation.

BRIEF DESCRIPTION OF THE DRAWINGS

[019] Additional objects and features of the present invention will become more apparent and the invention itself will be best understood from the following Detailed Description of Exemplary Embodiments, when read with reference to the accompanying drawings.

FIG. 1 is an overall view of a deflectable, high torque balloon catheter having a plurality of shaft sections and at least one slit tubular element with rows of slits constructed in accordance with the principles of the present invention.

FIG. 2 is a perspective view of a preferred slit tubular element on a shaft section of the deflectable, high torque flexible catheter at a non-bending state.

FIG. 3 is a cross sectional end view of a preferred slit tubular element on a shaft section of the deflectable, high torque flexible catheter.

FIG. 4 is a cross sectional view of a middle shaft section having a slit tubular element at a non-bending state.

FIG. 5 is a cross sectional view of a middle shaft section having a slit tubular element at a bending state.

FIG. 6 is a perspective view of another preferred slit tubular element on a shaft section of the high torque flexible catheter at a non-bending state.

FIG. 7 is a perspective view of another preferred slit tubular element on a shaft section of the high torque flexible catheter at a bending state.

DETAILED DESCRIPTION OF EXEMPLARY EMBODIMENTS

[020] What is shown in FIGS 1 to 7 is a preferred embodiment of the present invention. FIG. 1 shows an overall view of a deflectable, high torque catheter having a plurality of shaft sections and at least one slit tubular element of multi-directional deflectablity and torque transmitting assembly constructed in accordance with the principles of the present invention. The deflectable high torque balloon catheter comprises a flexible catheter shaft **1** having a distal shaft section **9**, a proximal shaft section **7** and a middle shaft section **8**, wherein each shaft section has

a distal end and a proximal end, wherein each shaft section is secured to its adjacent shaft section. Said catheter shaft has a distal end **2** and a proximal end **3**. A balloon **50** is attached to the distal shaft section **9** and is connected to a lumen tubing **52** extending from the balloon **50** to the proximal luer fitting **51**. Another separate lumen **53** extends from a second luer fitting **54** to the open ended distal tip **55**. A handle **4** is secured at the proximal end **3** of the proximal shaft section **7**. Said flexible balloon catheter shaft **1** has at least one main lumen **11** extending between the distal end **2** of the distal shaft section **9** and the proximal end **3** of the proximal shaft section **7**.

[021] At least one shaft section **7**, **8**, or **9** comprises a deflectable high torque transmission assembly for transmitting torque along said at least one shaft section, said deflectable high torque transmission assembly comprising a slit tubular element **18** that has a plurality of rows of slits **12** on said slit tubular element **18** and has sufficient deflectabililty and torque properties ensuring that a substantial fraction of the bending, rotational and displacement forces provided along said at least one shaft section are translated to bending, rotational and displacement forces at the distal end of said shaft section of the flexible catheter shaft **1**.

[022] The distal shaft section may be a fixed curve type or deflectable by employing a steering mechanism **5** at the handle **4**. A push-pull plunger **36** is employed to deflect the distal shaft section **9** of the flexible catheter shaft **1**. A connector **6** is connected at the proximal end of the handle **4**. At least one electrode **24** available for electrophysiology use is disposed on the distal shaft section **9**. The flexible catheter may further comprise a RF energy generator **23** and an electrical conductor **21, 22** secured to said RF energy generator **23** and said slit tubular element **18**, **28**, wherein the electrical conductor is adapted for transmitting RF energy from said RF energy generator to the at least one electrode **24** or the slit tubular element **18, 28**.

[023] FIG. 2 shows a perspective view of a preferred slit tubular element **18** on a shaft section of the deflectable high torque catheter at a non-bending state. A plurality of rows of slits **12** along with rows of anchors **17** are created along the slit tubular element **18**. The slit can

be created or arranged with respect to a longitudinal axis of said shaft section **7**, **8**, or **9** as selected from the group consisting of a perpendicular slit, an angled slit, a random slit, and a combination of the above thereof. The row of slits **12** can be created by a laser means, a mechanical means, or other suitable means.

[024] Each of the plurality of slits **12** has a slit starting point **13** at an outer surface **16** of the shaft section and two slit terminating points **14A**, **14B** at the outer surface away from the slit starting point **13**. At least one slit terminating point **14A, 14B** may be coupled with a small circular hole as shown in FIG. 2. Said small circular hole is for stress release when the slit tubular element is in a deflectable state. Each slit may penetrate through the inner surface **15** of the slit tubular element **18**. Each of the slit starting point **13, 13A,** or **13B** may be on the same side, on the opposite side, or randomly on the surface of the slit tubular element **18**. This is to accommodate longitudinal torque transmission along the slit tubular element and deflectability in a plurality of directions of the distal shaft section of this flexible catheter.

[025] FIG. 3 shows a cross sectional view of a preferred slit tubular element on a shaft section of the deflectable, high torque, flexible balloon catheter. Steering wires **20** run longitudinally along the said preferred slit tubular element through the anchors **17** located at various points within the slit tubular element **18**. One lumen tube **52** runs longitudinally from the balloon **50** to the luer fitting **51,** and another lumen tube **53** runs from the tip **2** to the second luer fitting **54**.

[025] FIG. 4 shows a cross sectional view of a middle shaft section having a preferred slit tubular element of FIG. 2 at a non-bending state. A distal end of the proximal shaft section **7** is firmly secured to a proximal end of a middle shaft section **8** at a joint region **19A**. Similarly, a proximal end of the distal shaft section **9** is firmly secured to a distal end of a middle section **8** at a joint region **19B**. The two sections can generally be secured together by adhesion, welding, screwing or other suitable means. An electrical conductor **21**, **22** passed through the lumen **11** of the flexible catheter **1** is adapted for transmitting electrical signal, energy, to and

from an electrode means to an external electrical equipment for signal sensing, pacing, cardioversion, defibrillation or RF energy delivery. FIG. 5 shows a cross sectional view of a shaft section having a slit tubular element **18** of FIG. 4 at a bending or deflection state.

[026] FIG. 6 shows a perspective view of another preferred slit tubular element on a shaft section of the deflectable, high torque flexible catheter at a non-bending state. At least one shaft section **7**, **8**, **9** comprises a deflectable, high torque transmission assembly for transmitting bending and torque along the at least one shaft section. The deflectable, high torque transmission assembly comprises a slit tubular element **28** that has at least one continuously spiraling slit **39** on said slit tubular element **28** and has sufficient deflectable and torque properties ensuring that a substantial fraction of the bending, rotational and displacement forces provided along the at least one shaft section are translated to bending, rotational and displacement forces at the distal end of the shaft section of the flexible catheter shaft, wherein the slit tubular element has a plurality of parallel slit members such as pairs of **40A-40B** or **40B-40C,** resulting from the at least one continuously spiraling slit **39**. In one embodiment, at least a portion **41** of at least one pair of adjacent slit members **40A-40B** is secured together.

[027] In a preferred embodiment, the slit tubular element **18**, **28** of the deflectable, high torque transmission assembly may be embedded within an elastic membrane, covered on an inner side of the slit tubular element, or covered on an outer side of the slit tubular element by an elastic membrane. In one further embodiment, the elastic membrane is to separate the interior lumen **11** of the slit tubular element **18**, **28** from an exterior surrounding of the slit tubular element. The elastic membrane may preferably be selected from the group of elastic material, inflatable balloon, or expandable membrane consisting of silicone, latex, polyurethane, thermoplastic elastomer such as Pebax brand polyether block amides, polyethylene balloon, cross-linked polyethylene balloon, permeable membrane, polyethylene terephthalate balloon, and the like. The slit tubular element **18**, **28** may be made of a material selected from the group consisting of polypropylene, polysulfone, platinum, stainless steel, Nitinol, gold, silver, iridium, tungsten, and their mixture thereof.

[028] FIG. 7 is a perspective view of another preferred slit tubular element on a shaft section of the deflectable, high torque flexible catheter of FIG. 6 at a bending or deflection state. Depending on which steering wire **20** is activated, the bending plane can differ. The slit tubular element **18** can only subject to the bending force or deflectability in the same direction of the slit **12** from the slit staring point **13** to the slit terminating points **14A, 14B**. In the case of a slit tubular element **28** comprising a continuously spiraling slit **39**, a plurality of securing portions or points **41** will make the slit tubular element **28** subject to the bending or deflection at a direction or a plane least resistance to restriction of the secured portion or portions **41**.

[029] From the foregoing, it should now be appreciated that an improved flexible balloon catheter having deflectable, high torque transmitting properties has been disclosed for cardiac and cardiovascular procedures. Particularly, the slit tubular element portion of the deflectable, high torque flexible balloon catheter is coupled with an electrical conductor for use in stimulating the human heart with pacing, cardioversion, defibrillation, and/or radiofrequency ablation therapy and is coupled with a balloon for blocking and positioning the catheter over the vessel orifice while contrast medium is injected through the distal tip. While the invention has been described with reference to a specific embodiment, the description is illustrative of the invention and is not to be construed as limiting the invention. Various modifications and applications may occur to those skilled in the art without departing from the true spirit and scope of the invention as described by the appended claims.